

## PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:  
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PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

		Date of mailing (day/month/year) <b>16 SEP 2008</b>
Applicant's or agent's file reference  58086-246999		<b>FOR FURTHER ACTION</b> See paragraph 2 below
International application No.  PCT/US07/16309	International filing date (day/month/year)  19 July 2007 (19.07.2007)	Priority date (day/month/year)  19 July 2006 (19.07.2006)
International Patent Classification (IPC) or both national classification and IPC  IPC: Please See Continuation Sheet USPC: 424/93.21;514/171,423,460		
Applicant  PARHAMI, FARHAD		

## 1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

## 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

## 3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US  Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Date of completion of this opinion  27 August 2008 (27.08.2008)	Authorized officer  Sreeni Padmanabhan, PhD., Telephone No. <i>571-272-1600</i>
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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US07/16309

**Box No. I Basis of this opinion**1. With regard to the **language**, this opinion has been established on the basis of:

- the international application in the language in which it was filed
- a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
- 2.  This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

a. type of material

- a sequence listing
- table(s) related to the sequence listing

b. format of material

- on paper
- in electronic form

c. time of filing/furnishing

- contained in the international application as filed.
- filed together with the international application in electronic form.
- furnished subsequently to this Authority for the purposes of search.

4.  In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

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<p style="margin: 0;">International application No. PCT/US07/16309</p>
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**Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims <u>1-40</u> _____ YES Claims <u>NONE</u> _____ NO
Inventive step (IS)	Claims <u>14-17, 29-31</u> _____ YES Claims <u>1-13, 18-28, 32-40</u> _____ NO
Industrial applicability (IA)	Claims <u>1-40</u> _____ YES Claims <u>NONE</u> _____ NO

**2. Citations and explanations:**

Claims 1-13, 18-28, and 32-40 lack an inventive step under PCT Article 33(3) as being obvious over US2003/0153541 ('541) in view of 2005/0095677 ('677). '541 teaches LXR agonists such as GW3965, as useful in treating various disorders including cancer (See for example paragraph [0028] and [0030]).

'541 does not expressly teach the use of TO901317. '541 does not expressly teach the method of screening LXR agonists.

'677 teaches TO901317 as LXR agonists (See paragraph [0041] for example).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ any known LXR agonist, including TO901317 and GW3965, in the treatment of cancer. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the screening method as claimed to identify LXR agonist.

One of ordinary skill in the art would have been motivated to employ any known LXR agonist, including TO901317 and GW3965, in the treatment of cancer since the use of LXR agonist in treating cancer is well-known. Reasonable expectation of success is present since TO901317 is a well-known LXR agonist.

Claims 1-40 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Claims 14-17 and 29-31 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest method of screening of LXR agonist by measuring hedgehog inhibition.

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**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.

Continuation of IPC:

**A61K 48/00( 2006.01),31/57( 2006.01),31/46( 2006.01),31/401( 2006.01),31/366( 2006.01)**  
**A61K 48/00( 2006.01),31/57( 2006.01),31/46( 2006.01),31/401( 2006.01),31/366( 2006.01)**